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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,821	11/13/2000	Todd M. Kinsella	A-70036/RMS/JJD	9149

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EXAMINER

TIZIO, STEVEN C

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/712,821

Applicant(s)

KINSELLA, TODD M.

Examiner

Steven C Tizio

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/13/01. 6) ☐ Other: \_\_\_\_\_

**Detailed Action**

1. Applicant's election without traverse of Group I (**claims 1-6**), drawn to a composition comprising a retroviral vector in Paper No. 9 is acknowledged.
2. **Claims 7-12** are withdrawn from consideration as not directed to the elected Group I.
3. **Claims 1-6** are pending.
4. **Claims 1-6** are currently being examined.
5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for **claims 1-12** of this application. The instant application, filed on 11/13/2000, has a filing date greater than one year of provisional application 60/165,189, filed on 11/12/99.
6. This application has been filed with informal drawings. Applicant is invited to notice that the draftsman in PTO 948 checked boxes 3, 5, 10, and 12. If applicant renumbers the figures, applicant is encouraged to amend the specification so that the description of renumbered figures corresponds to the renumbered figures.

7. The drawings are objected to because there are no separate Figure 15A and Figure 15B. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. The disclosure is objected to because of the following informalities:

- 1) page 1, line 18: "bonnd" should be "bond"
- 2) page 43, line 27: remove second "infected"

Appropriate correction is required.

#### **Claim Rejections - 35 USC § 112**

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **Claims 1-6** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The present claim is directed to "*a retroviral vector comprising nucleic acid encoding Heparin-binding epidermal growth factor-like growth factor (HBEGF) fused to nucleic acid encoding a green fluorescent protein (GFP).*" The specification does not disclose a specific sequence for the Heparin-binding epidermal growth factor-like growth factor (HBEGF).

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to any compound; which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics, to demonstrate possession of the claimed generic(s).

In the present instance, the claimed invention contains no identifying characteristics regarding the identity or sequence of the Heparin-binding epidermal growth factor-like growth factor (HBEGF).

### **Claim Rejections - 35 USC § 103**

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claims 1-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski *et al.* (WO9608274, published 3/21/96; provided by applicant in IDS, filed on 9/13/01) and Grignani *et al.* (Cancer Research, January 1, 1998, Vol.58, pp.14-19).

The claimed invention discloses a "*composition comprising a retroviral vector comprising a nucleic acid encoding Heparin-binding epidermal growth factor-like growth factor (HBEGF) fused to a nucleic acid encoding a green fluorescent protein (GFP)*".

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Sosnowski *et al.* teach "*conjugates of heparin-binding epidermal growth factor-like growth factor (HBEGF) linked, either directly or via a linker, to a targeted agent ... The targeted agent is a cytotoxic agent, such as a ribosome-inactivating protein (RIP) and an antisense nucleic acid, or is a therapeutic nucleic acid for targeted delivery. The targeted agent is attached to HBEGF, or via a linker, through a chemical bond, or the conjugate is prepared as a chimera using techniques of recombinant DNA*". (see abstract and Claim 1). Claim 22 teaches "*a plasmid, comprising DNA (DNA fragment comprising a sequence of nucleotides encoding the conjugate of any one of claims 1-4 and 6-15)*".

Sosnowski *et al.* do not teach HBEGF fused to green fluorescent protein and do not teach the use of a retroviral vector. Grignani *et al.* teaches, "*a retroviral expression vector (PINCO)... that contains the enhanced green fluorescence protein (GFP) controlled by a cytomegalovirus promoter*" (see abstract). According to Grignani *et al.* "*expression of the GFP yields a strong spontaneous fluorescent signal in heterologous cell types. It has been observed that GFP can be fused to resident proteins or to specific targeting signals without altering its fluorescence properties. GFP therefore seems to be a unique tool in cell biology, in that it allows specific proteins to be visualized in living cells or GFP-transfected cells to be identified.*" It would have been obvious to one skilled in the art to create a retroviral vector comprising the gene coding for HBEGF fused GFP with an IRES site, 2a site, and an IL-4  $\epsilon$  promoter. Such a construct can be used to monitor the expression of the HBEGF fusion protein.

### Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Tizio whose telephone number is (703) 305-1903. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**

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